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Docket No.: 00885/000D930-US0

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. :	09/155,740		
Applicant :	Deborah Ann Lewis, et al.	Art Unit.:	1761
Filed :	February 27, 1998	Examiner:	Helen F. Pratt
For :	FRUIT PRODUCTS		

- -

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APPELLANT'S REPLY BRIEF

Sir:

The Appellant hereby replies to the Examiner's Answer filed August 4, 2004 in the appeal of the above-identified patent application.

For the purposes of the ensuing discussion, it is noted that the present patent application defines water activity (AW) of a food as "the partial pressure of water in the food divided by the saturation pressure of water at the same temperature." The Food and Drug Administration provides a similar definition, but in terms that are somewhat more user friendly. It defines water activity of a food as:

> A ratio between the vapor pressure of the food itself, when in a completely undisturbed balance with the surrounding air media,

> and the vapor pressure of distilled water under identical conditions.

See the definition provided at http://www.fda.gov/ora/inspect_ref/itg/itg39.html, (copy attached as Exhibit A). Thus, water activity is a measure of the free water in the food. The definition F.D.A. notes that:

> Most foods have a water activity above 0.95 and that will provide sufficient moisture to support the growth of bacteria, yeast and mold. The amount of available moisture can be reduced to a point which will inhibit the growth of the organisms.

Reznik, U.S. Patent No. 3,741,106

The examiner admits the Reznik patent relates to a process for *hydrating* dried fruit. The fruit is fissured to permit rapid removal of air from the interior of the fruit so that the resulting vacuum produces rapid, forced impregnation of water into the interior of the fruit. Thus, the quantity of free water in the interior of the fruit increases (a high water activity). In contrast, the present invention seeks to reduce water activity by infusing a dried fruit with a solution containing water activity controlling solutes.

The examiner notes that the fruit in Reznik is reacted with water which contains a solute such as a preservative (sodium benzoate). A preservative is necessary in Reznik because the dates being processed have a free water content (water activity) which is high enough to support microbial life (See Column 2, Line 68 through Column 3, Line 5 of Reznik). Preservatives of this type are *not* water activity controlling solutes and are used at low concentrations, such as 0.1%. Sodium Benzoate is particularly undesirable, in that it is now banned as a food additive in many countries.

Furthermore, whereas Reznik forces water rapidly into a dried fruit through vacuum impregnation, the present invention causes solute infusion into the fruit. The McGraw-Hill Dictionary of Scientific and Technical Terms defines "infusion" as the "aqueous solution of a solute constituent of a substance as the result of the substances steeping in the solvent for a

period of time." Thus, the present invention contemplates a gradual introduction of solute into the dried fruit.

In any event, the present invention contemplates the limitation of free water in the fruit. For example, in example 5 of the present application, the water activity of raisins processed in accordance with the present invention is 0.21, which means there is insufficient free water to support microbial growth (a water activity of 0.5 or lower is considered to prevent the proliferation of any microorganisms) and infusion of water into the dried fruit is practically inhibited. So, modifying the process in Reznik so as to introduce water activity controlling solutes into the fruit would render the process of Reznik *unsatisfactorily* for its intended purpose.

Hsieh, U.S. Patent No.4,917,910

The Hsieh patent describes a process for introducing a liquid humectant to raisins by coating them with the liquid. In the Background Of the Invention, Hsieh demonstrates that in the preceding 50 years (Hsieh was filed April 6, 1988) there was a requirement to fulfill a long unmet need in the art for a simple, rapid and effective process for providing a dried fruit with the kinds of properties provided by the present invention. It was not until ten years later, that the present invention met that need.

The examiner characterizes Hsieh as disclosing that "it is known to infuse dried raisins with Aw (water activity) controlling solutes by tumbling the raisins in a humectant (Aw controlling solute)." Actually, the humectant is coated on the surface of the fruit (See Column 3, Lines 14-15; and Lines 49-51). In one of the embodiments, the coated raisins are subjected to mechanical processing specifically, Hsieh observes that "tumbling raisins in a bed of raisins will increase the liquid humectant surface carrying characteristics of the raisins" (Column 4, Lines 25-28). However, Hsieh warns that "gentle rolling action of the bed is preferred, and although the use of baffles in the tumbler is acceptable, the use of powered stirs should be avoided" (Column 13, Lines 32-34). Along the same lines Hsieh notes that the "[raisin] bed

should not be so deep as to compress the raisins to such an extent that the raisins are reduced to a pulpy mass" (Column 13, Lines 55-57).

The examiner cites this last passage as evidence that tumbling disrupts the structure of the fruit. However, taking the preceding quotes in context, it is clear that Hsieh cautions *against* disrupting the structure of the fruit in any way, but simply subjects it to gentle rolling. It is submitted that the examiner has misinterpreted Hsieh in this regard.

In contrast to Hsieh, independent Claim 1 of the present application calls for "disrupting the structure of the fruit...whilst maintaining integrity thereof" and independent Claim 2 recites subjecting the dried fruit "to a mechanical or physical process which causes cracks in the surface and/or edges of the fruit...whilst maintaining the essential structure and appearance of the fruit. Thus, the present claims contemplate the opposite of what Hsieh teaches, specifically, those skilled in the art would be dissuaded from disrupting the structure of the fruit based upon the disclosure of Hsieh.

The process in Hsieh involves three separate steps: a.) spraying the raisins with liquid humectants; b.) tumbling the raisins; and c.) allowing the raisins to stand. Hsieh notes that tumbling should take place for 1-2 hours (Col. 6, lines 17 and 18) and that standing should take place for "several weeks to a month" (Col. 6, line 20). The examiner optimistically refers to this standing period as being "within a few days. In contrast, as demonstrated by the examples in the present application, the time required for the process of the present invention is between 30 minutes and 4 hours (see claims 9 and 17).

Furthermore, the Hsieh process requires equipment for spraying the raisins and equipment for tumbling them. Such equipment is specialized and can be expensive. In contrast, the present invention uses only processing components that would be available in a conventional fruit processing production line.

GB 1,004,522 (Savage)

Savage relates to a process for drying vegetables, such as pulses (peas and beans) so that the resulting product "rehydrates more quickly" (Page 1, Line 12). According to this process, the skin is perforated before completion of drying (Page 1, Lines 68-69). Before drying has completed, the pulses are then impregnated with a solution of hydrophilic material. After the pulses have dried, they can later be rehydrated (as by cooking) more readily than untreated pulses.

Initially, it should be noted that the dehydration process and the impregnation process for pulses require different considerations than those for dry fruits. This is so because it is not necessary for the dry pulses to be edible directly, as they would usually be cooked for 15 minutes or more before consumption. In contrast, dried fruit is often eaten as a snack or incorporated into other foods, such as cereals. Therefore, the dried fruit must have a suitable texture and other properties for direct consumption. Thus the considerations in processing pulses and in processing dried fruit are completely different. Those skilled in the art would not consider a teaching in relation to treating pulses as being particularly relevant to the treatment of dried fruit.

Furthermore, the intended purpose of the Savage process is directly opposite to that of the process of the present invention. That is, Savage seeks to treat pulses so as to more readily absorb free water, whereas the present invention seeks to inhibit water activity (free water). As explained with respect to Reznik, if a water activity regulating solute were added to Savage, it would inhibit rehydration and render the Savage process unsatisfactory for its intended purpose.

The Rejections over Prior Art are Improper.

Claims 1-19 were rejected under 35 U.S.C. § 103(a) as obvious over Reznik in view of Hsieh and Savage. In making this rejection, the examiner concluded:

> [I]t would have been obvious to one of ordinary skill in the art to substitute the glycerol (solute) of Hsieh et al. or the impregnation solution of Savage '522 as the Aw controlling solute in the process of Reznik . . .

This overlooks the fact that, as shown in the preceding section related to the Reznik patent, adding a water activity controlling solute to Reznik would inhibit the water absorption properties of the fruit, rendering the modified process unsatisfactory for Reznik's intended purpose. If the proposed modification would render the prior art invention being unmodified unsatisfactorily for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon, 733 F.2d 900 (Fed. Cir. 1984).* Thus, there is no suggestion or motivation to make the modification proposed by the examiner, as a matter of law.

Furthermore, as was demonstrated in the preceding discussion of the Hsieh patent, this patent teaches that the physical structure of the fruit should *not* be disrupted. Thus, not only is there no suggestion or motivation to make the modification proposed by the examiner, but Hsieh specifically teaches directly away from its being used in a process where the physical structure of the fruit is modified. Thus, those skilled in the art would be led away from combining Hsieh with Reznik.

The Examiner also proposes modifying Reznik in accordance with the disclosure of Savage. As pointed out in the preceding section with respect to Savage, those skilled in the art would not look to a process for the treatment of pulses for anything pertinent to the treatment of fruits. Nevertheless, for the sake of argument, even if the combination were made, it would still not lead to the present invention. The present invention contemplates the infusion of solutes which regulate water activity. To the contrary, Reznik and Savage both seek to maximize rehydration. A water activity regulator would render both Reznik and Savage unsatisfactorily for their fundamental intended purpose.

The applicants' main brief has set forth grounds for the separate patentability of Claim Groups I, II, III and IV. The examiner has offered no convincing argument why the features

of Groups III and IV do not render the claims patentable.for the reasons presented in the main brief.

Responses to Examiner's Arguments.

Arguing that Reznik is merely relied on to teach that it is known to fissure a date, the examiner attempts to minimize the different fundamental purposes between Reznik and the present invention: the fact that Reznik is addressed to maximizing rehydration whereas the present invention and Hsieh are addressed to reducing free water content or water activity. However, as discussed above, this is decidedly not the nature of the present rejection. The examiner has rejected the claims on the ground that it would have been obvious to modify Reznik in accordance with the teachings of Hsieh or Savage. The incorrectness of this position has been demonstrated above.

The examiner insists that since Reznik and Savage disclose fissuring, it would be obvious to use fissuring to add water activity reducing ingredients, relying on the disclosure of Hsieh. However, the only disclosure for fissuring is in the two references, Reznik and Savage, which seek to enhance rehydration (i.e., maximize water activity). The suggestion to add the water activity lowering ingredients of Hsieh to either Reznik or Savage would modify those processes so as to render them unsatisfactory for their intended purpose.

The examiner asserts that "it is not seen how infusion is different from vacuum impregnation because no rate of infusion is claimed." The dictionary definition of infusion makes it clear that it involves a natural steeping process. In contrast, vacuum impregnation amounts to the forceful injection of water into the fruit. This is basically the difference between soaking in a liquid and forcefully injecting the liquid. It should therefore be clear that the use of the term "infusing" excludes any forceful impregnation.

The examiner appears to agree that processes dealing with pulses, such as Savage, are fundamentally different from processes for dried fruits. The examiner notes that "one would assume that the skin of the pulse is tough or it would not need perforating in order to rehydrate

it, just as the skin of a dried date is hard and needs to be fissured in order to rehydrate it." In contrast, the skins of dried fruits under consideration here do not tend to be tough, so those skilled in the art would not necessarily consider perforating their surface in order to treat them. The examiner's sweeping observation that "even though the end products of these references are different it is still known to achieve more efficient impregnation by puncturing or pricking skins" is an assumption based on hindsight and does not accurately consider what each of the references teaches.

The examiner asserts "that it is not seen that the examiner is using hindsight reconstruction because the combined references clearly teach that the claimed method of infusing is known." "The mere fact that the prior art may be modified in a manner suggested by the examiner does not make the modification obvious unless the prior art suggests the desirability of the modification." *In re Fritch 23 U.S.P.Q. 2d 1780, 1783 (Fed. Cir. 1992).* However, it has been clearly demonstrated above that not only does the prior art not suggest the modification, but that the modification would specifically *not* be made by those skilled in the art.

Conclusion

For all of the above reasons, the examiner should be reversed as to the unpatentability of all of the claims presently in this Appeal.

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Respectfully submitted,

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Appellant's Reply Brief (9 Pages w/Exhibit A (6 Pages));
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DEPT. OF HEALTH, EDUCATION, AND

WELFARE PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION

ORA/ORO/DEIO/IB

Date: 4/16/84 Number: 39

Related Program Areas: Foods

ITG SUBJECT: WATER ACTIVITY (a w) IN FOODS

DEFINITION

The water activity (a w) of a food is the ratio between the vapor pressure of the food itself, when in a completely undisturbed balance with the surrounding air media, and the vapor pressure of distilled water under identical conditions. A water activity of 0.80 means the vapor pressure is 80 percent of that of pure water. The water activity increases with temperature. The moisture condition of a product can be measured as the equilibrium relative humidity (ERH) expressed in percentage or as the water activity expressed as a decimal.

Most foods have a water activity above 0.95 and that will provide sufficient moisture to support the growth of bacteria, yeasts, and mold. The amount of available moisture can be reduced to a point which will inhibit the growth of the organisms. If the water activity of food is controlled to 0.85 or less in the finished product, it is not subject to the regulations of 21 CFR Parts 108, 113, and 114.

SORPTION BEHAVIOR

The bacterial cell can only transfer nutrients in and waste materials out through the cell wall. The materials, therefore, must be in soluble form to permeate the cell wall. A portion of the total water content present in food is strongly bound to specific sites and does not act as a solvent. These sites include the hydroxyl groups of polysaccharides, the carbonyl and amino groups of proteins, and others on which water can be held by hydrogen bonding, by ion-dipole bonds, or by other strong interactions. The binding action is referred to as the sorption behavior of the food. The most successful method for studying the sorption properties of water in food

products has been the preparation of "Sorption Isotherms," or curves relating the partial pressure of water in the food to its water content at constant temperature. The same practice is followed to study curves relating water activity under equilibrium conditions to water content.

Two basic methods can be used to obtain the constant temperature sorption curves. In the first method, food of known moisture content is allowed to come to equilibrium with a small headspace in a tight enclosure and partial pressure of water activity is measured manometrically, or relative humidity is measured using a hyqrometer. Water activity is equal to equilibrium relative humidity divided by 100: (a w = ERH/100) where ERH is the equilibrium relative humidity (%). Relative humidity sensors of great variety are available for this purpose, including electric hygrometers, dewpoint cells, psychrometers, and others.

A second basic method for preparing isotherms is the exposure of a small sample of food to various constant humidity atmospheres. After equilibrium is reached, the moisture content is determined gravimetrically or by other methods. A number of saturated salt solutions are available for this purpose. Saturated salt solutions have the advantage of maintaining a constant humidity as long as the amount of salt present is above saturation level. Salt slushes and solutions of glycerol or sulfuric acid are among those commonly used.

Knowledge of sorption behavior of food is useful in concentration and dehydration processes for two reasons:

1. It is of importance in design of the processes themselves; because it has an important impact on the ease or difficulty of water removal, which depends on the partial pressure of water over the food and on the energy of binding of the water in the food.
2. Water activity affects food stability and therefore it must be brought to a suitable level at the conclusion of drying and maintained within an acceptable range of activity values during storage.

Products containing free water give off moisture in vapor form to the air in the environment, only when the vapor pressure in the air is below that of the product. The vapor pressure of a salt or sugar solution is reduced in comparison to that of pure water. The amount of vapor in the surrounding air generally is measured as relative

humidity. At the equilibrium point, water is neither given off nor absorbed. The vapor pressure of the food product then becomes identical to that of the surrounding air.

MEASUREMENT EQUIPMENT

The equipment suitable for the measurement of water activity can be the same as that used for the measurement of relative humidity provided that the sensing element used can be made captive or otherwise isolated with a sample of the product to be measured. A basic measuring technique utilizes a sealed dish or container with the sensor mounted above the test sample.

For initial screening purposes, all FDA district laboratories are equipped with the Abbeon a w-Value Analyzer (a hair hygrometer). Samples can be tested in duplicate. The instruments are used to set up a reference chart with data obtained from checks of reliable humidity generators. Salt slushes of known a w values such as sodium chloride, potassium nitrate, and potassium sulfate can be used. These salts will give a range of water activity (at 25 C) from 0.758 to 0.969. The results of this test are an approximation which should then be confirmed by measurement, using pressure equilibrium techniques in which the sample is allowed to come to equilibrium with a reference standard, such as a microcrystalline cellulose (MC). Electronic instruments suitable for confirmation tests are:

1. Beckman Hygroline Moisture Meter; Nova Sina/Rotronic Moisture-Humidity Meters
2. Hygrodynamic Hygrometer
3. WeatherMeasure Relative Humidity System

The critical factors in the control of water activity as an adjuvant in preservation are the ingredients in the final product and their effect on water binding capacity which is measured by the ERH (water activity, a w).

In determining the ERH (a w) several hours are required for the water vapor (relative humidity) to reach equilibrium in the headspace above the food in the closed container. Therefore, the formulation of the product to give the required a w must be predetermined and very accurately compounded at the time of packing. It is necessary for the analyst to ensure that the temperature of the supernatant air above the sample be closely controlled, as even a slight difference in temperature in this area can result in a significant change in water activity

reading. Stoloff (1978) states that at 25 C, a 0.1 C difference between the solid or liquid sample and the supernatant air will result in an approximate 0.005 difference in water activity measurement.

Allowing the temperature between the sample air interface and the supernatant air to vary, for example, by 1 C (approximately 1.8 F) could result in a difference in a w reading of 0.05. Considering that the minimum a w for the growth of C. botulinum is approximately 0.93, such a temperature differential could result in an erroneous reading for the sample of less than 0.93. Thus, the necessity of ensuring a suitable temperature control mechanism for the containment vessel (air cabinet or water bath) in which the testing chambers (e.g. glass jars) contain the sample repose.

REGULATIONS

The water activity level of 0.85 is used as a point of definition for determining whether a low-acid canned food or an acidified food is covered by the regulations. Low-acid canned foods can be preserved by controlling water activity at levels above 0.85. The minimum a w level for the growth of C. botulinum is approximately 0.93. Depending on various product characteristics this minimum level can be as high as 0.96. The regulations (21 CFR 113.3(e) (1) (ii)) state that commercial sterility can be achieved by the control of water activity and the application of heat. The heat is generally necessary at a w levels above 0.85 to destroy vegetative cells of microorganisms of public health significance (e.g., staphylococci) and spoilage microorganisms which can grow in a reduced a w environment. (See also the following other sections of the regulations which deal with a w controlled products:

21 CFR 113.10 - Attendance at an approved school giving instruction appropriate to the preservation technology involved.

21 CFR 113.40(i) - Equipment and procedures for thermal processing of foods where critical factors such as water activity are used.

21 CFR 113.81(f) - Additional factors to be controlled to prevent the growth of microoganisms not destroyed by the thermal process.

21 CFR 113.100(a) (6) - Record keeping requirements for a w determinations.

Some examples of water activity controlled low-acid

canned foods, that may have an a w of greater than 0.85, are: canned cake, bread, bean paste, some chutney, salted vegetables, salted fish, guava paste, lupini beans, syrup, toppings, puddings, and some oriental specialty sauces. Water activity is usually controlled by the use of salt or sugar. There are situations where routine a w determinations need not be made during production. For example, if salt is the preservative, percent salt determinations alone may be sufficient to document control of water activity and commercial sterility. However, the processor or the processing authority would need to have data which consistently relates salt levels in the particular product to a w levels. Water activity could also be controlled by formulation as long as the formulation is related to a given a w level by sufficient data. Since changes in ingredients suppliers may change the a w of the finished product, periodic a w determinations by the processor would be appropriate.

WATER ACTIVITY (a w) OF SOME COMMON FOODS

Liverwurst	0.96
Cheese Spread	0.95
Red Bean Paste	0.93
Caviar	0.92
Fudge Sauce	0.83
Soft Moist Pet Food	0.83
Salami	0.82
Soy Sauce	0.80
Peanut Butter 15% total moisture	0.70
Dry Milk 8% total moisture	0.70

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